

Application Ser. No.: 10/019,588
Filing Date: December 20, 2001
Examiner: Fubara, Blessing M.

Amendment Pursuant to 37 C.F.R. § 1.121

IN THE CLAIMS:

The claims set forth below with amendments as indicated will replace all prior versions and listing of claims in the application.

Claim 1. (Currently amended): A delayed release coated core which produces a timed pulse release containing an active substance in its core and a polymer coating comprising an ammonio methacrylate copolymer, said core further containing a ~~cationic or~~ zwitterionic surfactant in an amount of from 10% to 50% relative to the amount of ammonio methacrylate copolymer in the coating.

Claim 2. (Cancelled)

Claim 3. (Previously presented): A delayed release coated core according to claim 1 wherein the ammonio methacrylate copolymers are of type A or B.

Claim 4. (Currently amended): A delayed release coated core according to Claim 3 wherein the ~~cationic surfactant is chosen from trimethyl dimyristoyl ammonium propionate, dimethyl dioctadecyl ammonium bromide, trimethyl cetyl ammonium bromide, dimethyl didodecyl ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the~~ zwitterionic surfactant is chosen from N-alkylbetaines, N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

Claim 5. (Cancelled)

Claim 6. (Previously presented): A delayed release coated core according to claim 4 wherein the zwitterionic surfactant is cocamidopropylbetaine.

Application Ser. No.: 10/019,588
Filing Date: December 20, 2001
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Claim 7. (Previously presented): A delayed release coated core according to Claim 3 wherein the active substance is chosen from diltiazem, theophylline, felodipine, verapamil, clonidine, acebutolol, alprenolol, betaxolol, metoprolol, nadolol, propranolol, timolol, captopril, enalapril, fosinopril, tiapamil, gallopamil, amlodipine, nitrendipine, nisoldipine, nicardipine, felodipine, molsidamine, indomethacin, sulindac, indoprofen, ketoprofen, flurbiprofen, fenbufen, fluprofen, diclofenac, tiaprofenic acid, naproxen, mizolastine, terbutaline, salbutamol, betamethasone, prednisone, methylprednisolone, dexamethasone, prednisolone, sumatriptan, naratriptan, cimetidine, ranitidine, famotidine, nizatidine, omeprazole, morphine, fenoprofen, ibuprofen, ketoprofen, alclofenac, mefenamic, alfuzosin, prazosin, tamsulosin, levodopa and methyldopa, their salts and pharmacologically active esters.

Claim 8. (Previously presented): A delayed release coated core according to Claim 3 in the form of a particle, pellet, bead, granule or spheroid, of a diameter comprised between 0.3 and 3 mm.

Claim 9. (Previously presented): A delayed release coated core according to Claim 3 in the form of a tablet or a minitablet.

Claim 10. (Cancelled)

Claim 11. (Previously presented): A delayed release coated core according to Claim 3 wherein the core is separated from the polymer coating by a layer of water soluble polymer.

Claim 12. (Previously presented): A delayed release coated core according to claim 11 wherein the soluble polymer is chosen from hydroxypropylmethylcellulose, hydroxyethylcellulose and polyvinylpyrrolidone.

Claim 13. (Previously presented): A pharmaceutical dosage form comprising a delayed release coated core according to Claim 3.

Application Ser. No.: 10/019,588
Filing Date: December 20, 2001
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Claim 14. (Previously presented): A pharmaceutical dosage form according to claim 13 in the form of a tablet, a multilayer tablet, a multicoated tablet or a capsule.

Claim 15. (Previously presented): A pharmaceutical dosage form according to claim 13 wherein coated cores of differing delayed release times are combined together to give a stepped release profile.

Claim 16. (Previously presented): A pharmaceutical dosage form according to claim 13 wherein the delayed release coated core is combined with a sustained release entity or immediate release entity.

Claim 17. (Previously presented): A pharmaceutical dosage form according to claim 16 wherein said sustained release entity or immediate release entity contains an active substance different from the active substance in the delayed release coated core.

Claim 18. (Previously presented): A pharmaceutical dosage form according to claim 16 wherein a first release pulse occurs immediately and a second release pulse is delayed for a fixed time.

Claim 19. (Previously presented): A capsule according to claim 35 comprising a delayed release coated core in the form of a particle, pellet, bead granule or spheroid having a diameter of 0.3 to 3 mm or in the form of a minitablet, and an immediate and/or sustained release entity chosen from

- (i) immediate release particles or minitablets or an immediate release granulate or powder, and
- (ii) controlled release particles or minitablets.

Claim 20. (Previously presented): A tablet according to claim 35 wherein the delayed release coated core in the form of a particle, pellet, bead granule or spheroid having a diameter of 0.3 to 3 mm is imbedded in a rapidly disintegrating matrix.

Claim 21. (Previously presented): A capsule according to claim 35 comprising one or more immediate release tablets and one or more delayed release coated cores in the form of tablets.

Claim 22. (Previously presented): A multicoated tablet according to claim 35 coated with an immediate release soluble or disintegrable coating.

Claim 23. (Previously presented): A tablet according to claim 20 wherein the matrix is free of active substance.

Claim 24. (Cancelled)

Claim 25. (Previously presented): A tablet according to claim 20 wherein sustained release particles are mixed with the delayed release coated particles.

Claim 26. (Previously presented): A tablet according to claim 20 wherein immediate release particles are mixed with the delayed release coated particles.

Claim 27. (Previously presented): A tablet according to claim 20 wherein the delayed release coated particles are further coated with a layer containing the active substance.

Claim 28. (Previously presented): A tablet according to claim 20 comprising one or more layers containing the delayed release particles in the rapidly disintegrating matrix and one or more layers containing the active substance in an immediate release matrix.

Claim 29. (Previously presented): A delayed release coated core according to Claim 3, said core further containing a pharmaceutically acceptable organic acid.

Claim 30. (Previously presented): A delayed release coated core according to claim 4, said core further containing an acid chosen from maleic, tartaric, malic, fumaric, lactic, citric, adipic and succinic acid or a salt thereof.

Application Ser. No.: 10/019,588
Filing Date: December 20, 2001
Examiner: Fubara, Blessing M.

Claim 31. (Previously presented): A delayed release coated core according to claim 30 wherein the acid is chosen from tartaric, fumaric, citric and succinic acid or salt thereof.

Claim 32. (Previously presented): A delayed release coated core according to claim 31 wherein the acid is succinic or tartaric acid and the surfactant is cetylpyridinium chloride or cocamidopropylbetaine.

Claim 33. (Previously presented): A delayed release coated core according to claim 32 wherein the active substance is alfuzosin or an acid-addition salt thereof.

Claim 34. (Cancelled)

Claim 35. (New): A pharmaceutical dosage form according to claim 14 wherein the delayed release coated core is combined with a sustained release entity or immediate release entity.